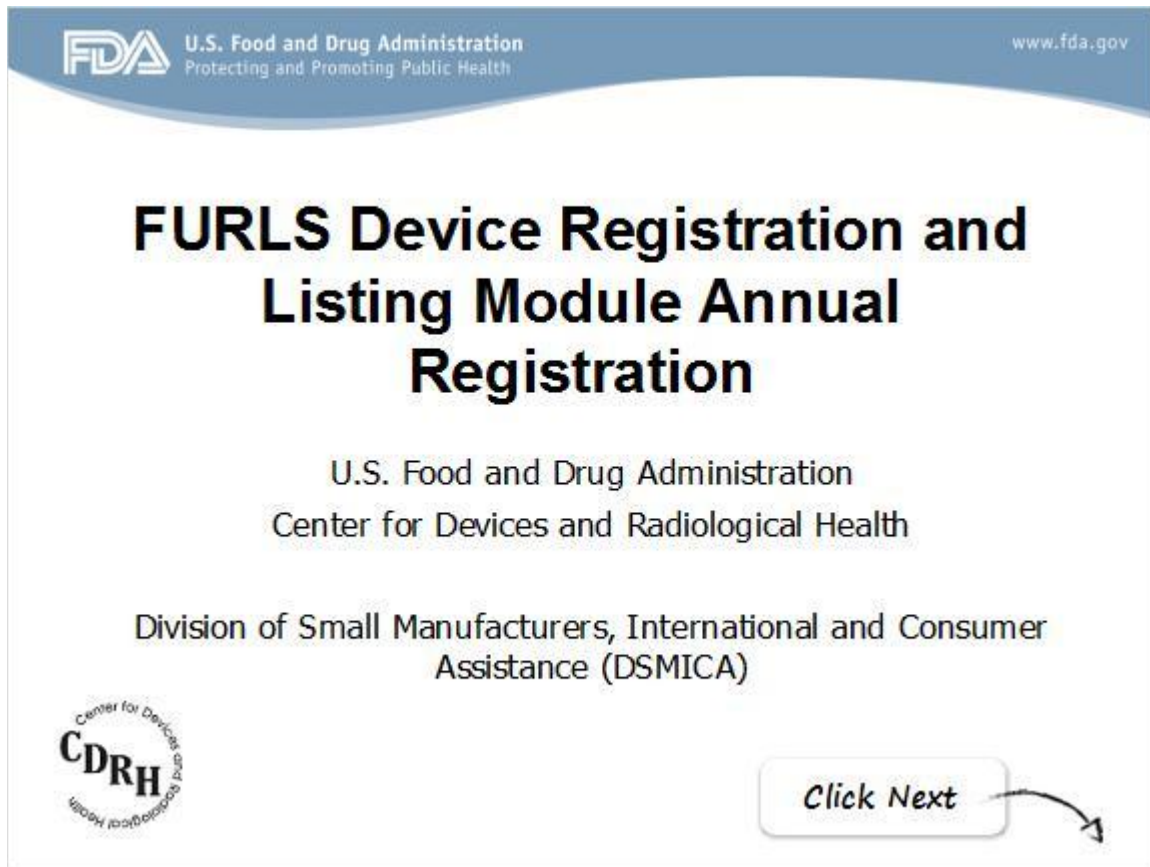


Welcome



The screenshot shows the title page of a tutorial. At the top is a blue header with the FDA logo, the text "U.S. Food and Drug Administration Protecting and Promoting Public Health", and the website "www.fda.gov". The main title "FURLS Device Registration and Listing Module Annual Registration" is centered in large, bold, black font. Below it, the text "U.S. Food and Drug Administration Center for Devices and Radiological Health" is centered. Further down, "Division of Small Manufacturers, International and Consumer Assistance (DSMICA)" is centered. In the bottom left is the CDRH logo. In the bottom right is a button labeled "Click Next" with a curved arrow pointing to the right.

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

FURLS Device Registration and Listing Module Annual Registration

U.S. Food and Drug Administration
Center for Devices and Radiological Health

Division of Small Manufacturers, International and Consumer Assistance (DSMICA)

CDRH Center for Devices and Radiological Health

Click Next

Notes:

This tutorial will show you how to complete the annual registration of a medical device facility.

Navigation

The screenshot shows the top of a tutorial window. At the top left is the FDA logo with the text "U.S. Food and Drug Administration" and "Protecting and Promoting Public Health". At the top right is the URL "www.fda.gov". Below the header, on the right, is a button labeled "Resources" with a hand-drawn arrow pointing to it from the text "Click Next for instructions" in a separate box. The main content area has a section titled "Instructions, Notes, & Audio" followed by a paragraph: "As you move through the tutorial, you have the option of viewing the instructions in plain text or with images. For a print copy of the instructions, click the Resources tab on the upper right corner of the player window." Below this is another paragraph: "To adjust or turn off audio, use your computer's volume control. To read the narrative, click on the Notes tab next to the menu." This is followed by a section titled "Navigation" and a paragraph: "Click Next or Prev to move through the tutorial. You can also use the left menu and click on a specific topic." In the bottom left corner is the CDRH logo (Center for Devices and Radiological Health). In the bottom right corner is a box with the text "Click Next for instructions" and a hand-drawn arrow pointing to the "Resources" button.

Resources

Instructions, Notes, & Audio

As you move through the tutorial, you have the option of viewing the instructions in plain text or with images. For a print copy of the instructions, click the Resources tab on the upper right corner of the player window.

To adjust or turn off audio, use your computer's volume control. To read the narrative, click on the Notes tab next to the menu.

Navigation


Click Next or Prev to move through the tutorial. You can also use the left menu and click on a specific topic.

Click Next for instructions

Notes:

You have the option of viewing the instructions in text or with images in this tutorial. You can also print the instructions by clicking Resources located in the upper corner of the slide.


Instructions

 U.S. Food and Drug Administration
Protecting and Promoting Public Health

www.fda.gov

Follow these steps to access FURLS or click next to see instructions with images:

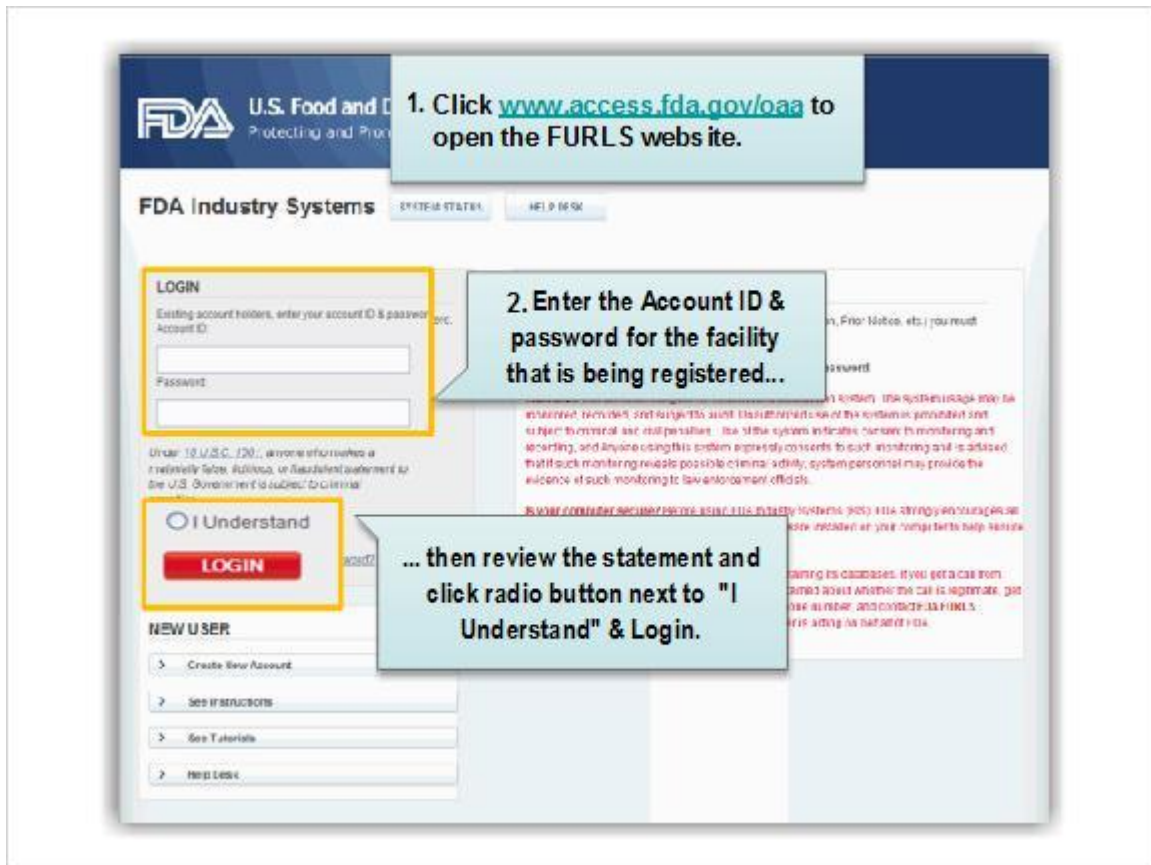
1. Click www.access.fda.gov/oa to open the FURLS website in a new browser window.
2. Enter your account ID and password, review the statement, click the radio button next to "I Understand," and "Login" to open the Account Management page.
3. Click "Device Registration & Listing" to open the Important Messages page.
4. When you have your Payment Identification Number (PIN) and Payment Confirmation Number (PCN), click Continue. If you don't have your PIN & PCN, you will need to pay the annual fee on the DFUF Website. It will take at least 48 hours to receive your PCN. Then return to the FURLS website to complete your annual registration.
5. Click "Annual Registration" to open the View Registrations page.
6. Click the radio button next to the facility you wish to re-register, then click "Re-register selected establishment" to open the Review Registration Information page.
7. Review the information to ensure accuracy. Edit as needed, then click "Continue" to open the Review Registration Information page. If no edits are needed, scroll down to Certification Statement.
8. Review the Certification Statement and click the checkbox and then "Submit." If an error message pops up, click the checkbox next to the statement before resubmitting.
9. Enter the PIN & PCN and click Submit.
10. Return to the "Main Menu" to re-register another facility or "Account Management" to log out.

Click Next to view
instructions with images 

Notes:

You can start here with the text instructions, or click next to view instructions with images.

Login



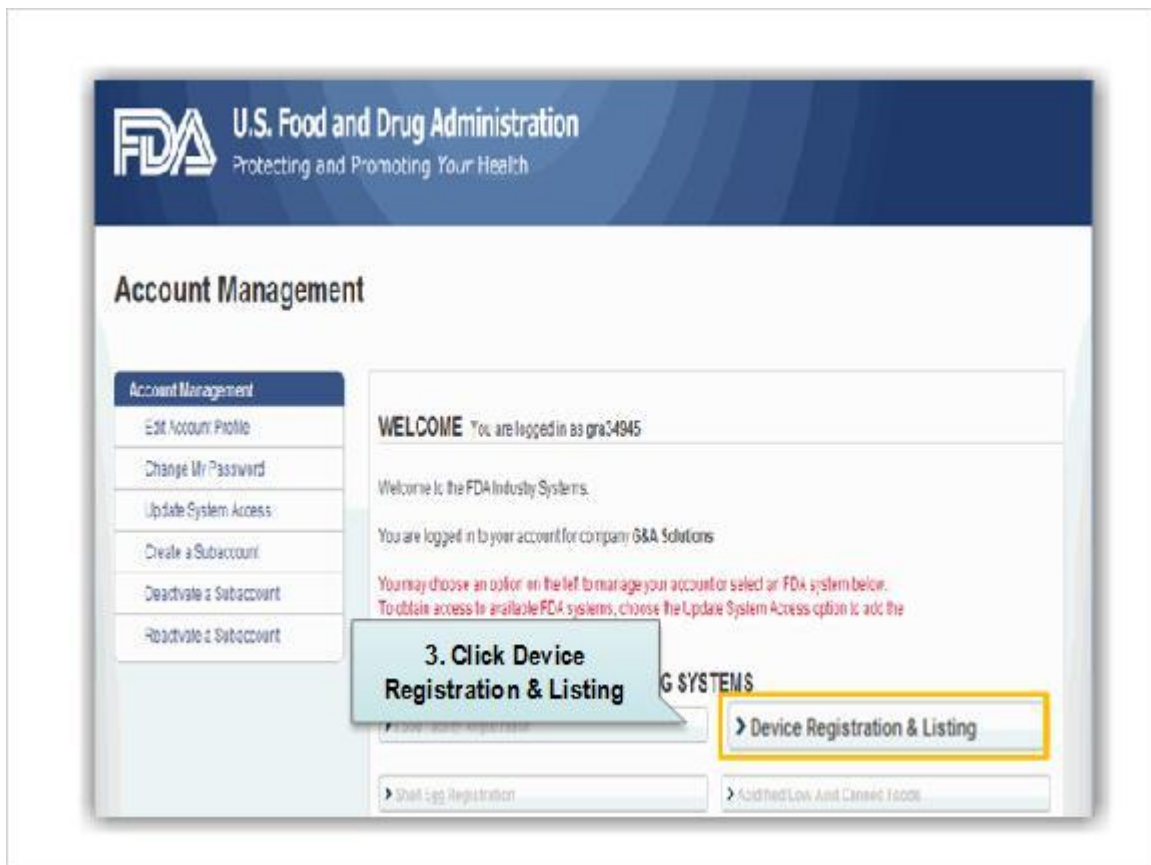
Notes:

For best results, review these instructions with the FURLS website open in another browser window.

1. Go to www.access.fda.gov/oaa to open the FURLS login page.

2. Enter your Account ID & password for the facility that is being registered, then click the radio button next to "I understand" and "Login."

Login



Notes:

3. On the Account Management page, click "Device Registration & Listing" to open the Important Messages page.

Login



Notes:

If you have not paid the annual registration fee, you will not be able to complete the annual registration. You will need to click "visit this website" to open the DFUF Website. After you have received your Payment Identification Number (PIN) and Payment Confirmation Number (PCN), return to the FURLS website to complete your annual registration. Note that it takes at least 48 hours to receive an email with the PCN.

4. When you have your PIN & PCN, click "Continue" to open the DRLM Main Menu.

DRLM Main Menu

The image shows two screenshots of the DRLM (Device Registration & Listing Module) interface. The top screenshot is the 'DRLM Main Menu' with a callout box stating: '5. Click Annual Registration to open the View Registrations page.' The bottom screenshot is the 'View Registrations' page, showing a table of facilities with a callout box stating: '6. Click the radio button for the facility to be re-registered...' and another callout box stating: '...then click Re-register Selected Establishment.' The table lists two facilities: Grady East Manufacturing and Grady Imports, both with 'Yet Assigned' registration status. A button labeled 'RE-REGISTER SELECTED ESTABLISHMENT' is highlighted.

DRLM Main Menu

Important Notice: You have not yet received your Payment Confirmation Number (PCN) and will need to return to the FDA User Fee website to register your facility prior to registering. If you have not yet received your PCN, you will need to return to the FDA User Fee website to register your facility prior to registering. If you have not yet received your PCN, you will need to return to the FDA User Fee website to register your facility prior to registering.

Annual Registration

[View Your Registration and Listing Information](#)

[Download Your Listing Information](#)

DRLM View Registrations

Annual Registration Information

Important Notice: You must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you have not yet received your Payment Confirmation Number (PCN), you will need to return to the FDA User Fee website to register your facility and will need to return to the FDA User Fee website to re-enter all information for the facility. You must pay the annual registration user fee for all transfers of ownership, regardless of whether the previous owner has already paid an annual registration user fee for the current fiscal year.

Select	Name And Address	Registration/FEI Number
<input type="radio"/>	Grady East Manufacturing 7001 Zongchun Road, B Building, Suite 51 Shanghai, Shanghai, 201101, CHINA	Yet Assigned
<input type="radio"/>	Grady Imports 12345 Rodville Pike Rodville, Maryland, 20852, UNITED STATES	Yet Assigned

[CANCEL - RETURN TO MAIN MENU](#) [RE-REGISTER SELECTED ESTABLISHMENT](#) [DEACTIVATE SELECTED ESTABLISHMENT](#)

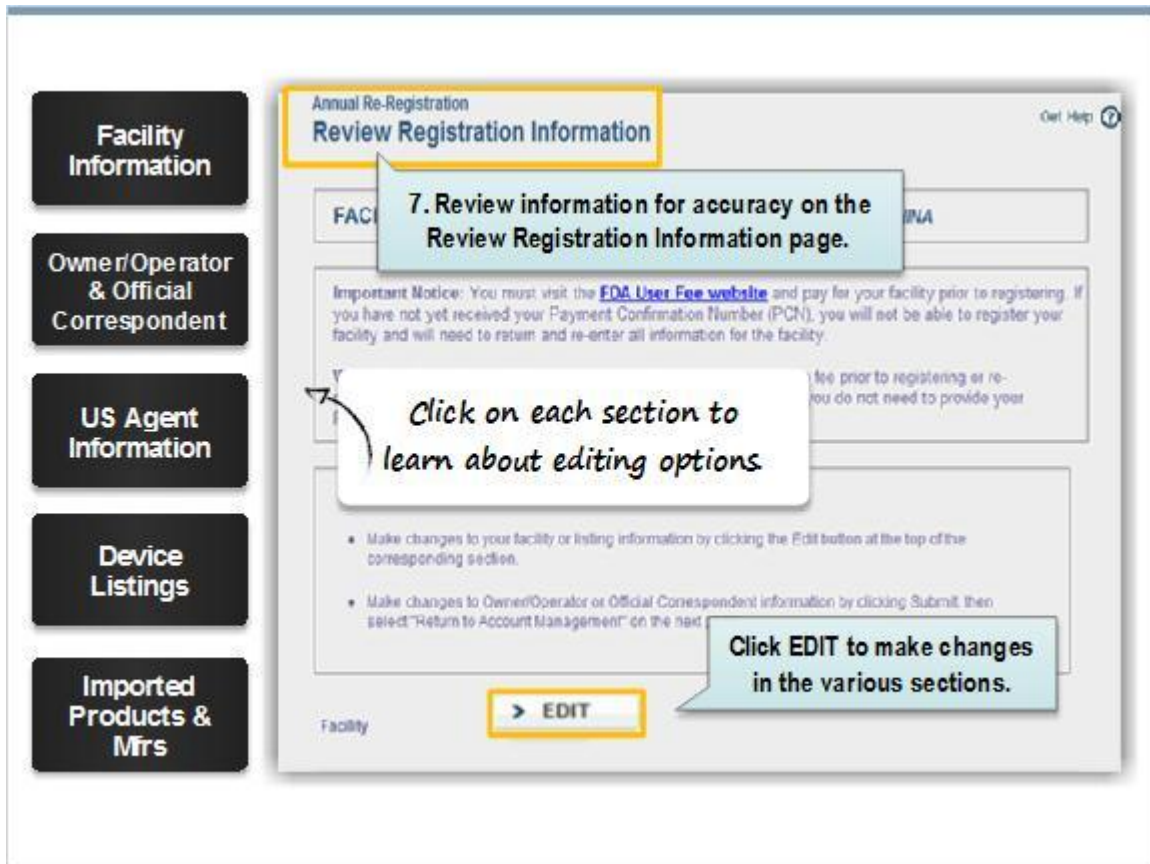
Notes:

5. On the DRLM Main Menu page click "Annual Registration" to open the DRLM View Registration page.

6. On the View Registrations page, click on the radio button next to the facility to re-register, then click Re-register Selected Establishment to open the Review Registration Information page.

Note: If the facility that you want to select is visible but the radio button is grayed out, you will need to contact the owner/operator contact person and ask to be assigned as the official correspondent. If the facility is missing from the page, return to the DRLM main menu and click "view your registration and listing information" to ensure the annual registration was completed. If the facility is not listed, contact the CDRH Registration and Listing Helpdesk.

Editing



Notes:

7. You have a number of editing options to update information. To learn more about editing each section, click on the topic buttons.

Click "EDIT" on each section to edit the specified information.

Click "Continue" when you are done editing to go back to the Review Registration Information page and scroll down to the Certification Statement.

Facility Information

The screenshot displays a web interface for facility information. On the left, a vertical sidebar contains five buttons: 'Facility Information', 'Owner/Operator & Official Correspondent', 'US Agent Information', 'Device Listings', and 'Imported Products & Mfrs'. The main content area shows the 'Facility' tab with a yellow-bordered 'EDIT' button. Below this, a form displays facility details: Registration Number (N), Initial Importer (Grady East), Facility Name (7001 Zongchun Road), Address (B Building, Suite 512), DUNS Number (201101), Foreign Trade Zone (Shanghai), and Annual Re-Registration (Shanghai). A blue callout box with a speech bubble icon states: 'To correct facility information, click EDIT to open Update Facility Information.' Below the facility details, the 'Update Facility Information' form is shown. It includes a red warning: 'Fields marked with an asterisk (*) are required.' The form fields are: 'Choose Country/Area where Facility is Located:' (CHINA), 'Facility Name:*' (Grady East Manufacturing), 'Address Line 1:*' (7001 Zongchun Road), 'Address Line 2:' (B Building, Suite 512), 'Postal Code:*' (201101), 'City:*' (Shanghai), 'Foreign State:*' (Shanghai), and 'Choose a Province / Territory'. At the bottom, there are sections for 'Phone:' and 'Fax:' with fields for Country Code, Area/City Code, and Phone/Fax Number.

Facility [> EDIT](#)

Registration Number: N
Initial Importer: Grady East
Facility Name: 7001 Zongchun Road
Address: B Building, Suite 512
DUNS Number: 201101
Foreign Trade Zone: Shanghai
Annual Re-Registration: Shanghai

To correct facility information, click EDIT to open Update Facility Information.

Update Facility Information [Get Help](#)

Fields marked with an asterisk (*) are required.

Choose Country/Area where Facility is Located:* CHINA

Facility Name:* Grady East Manufacturing

Address Line 1:* 7001 Zongchun Road

Address Line 2: B Building, Suite 512

Postal Code:* 201101

City:* Shanghai

Foreign State:* Shanghai

[Choose a Province / Territory](#)

Phone: Country Code: Area/City Code: Phone Number: Extension:
86

Fax: Country Code: Area/City Code: Fax Number:
86

Notes:

Facility Information: Click "EDIT" to update facility information. However, if the country/area needs editing, you will need to contact the CDRH Registration & Listing Helpdesk.

Owner/Operator and Official Correspondent

The screenshot displays the FDA registration portal interface. On the left, a vertical navigation menu contains five black buttons with white text: 'Facility Information', 'Owner/Operator & Official Correspondent' (which is highlighted with a yellow border), 'US Agent Information', 'Device Listings', and 'Imported Products & Mfrs'. The main content area shows the 'Review Registration Information page.' with two stacked form sections. A light blue callout box at the top of the forms contains the text: 'Instructions for how to edit the owner/operator and official correspondent information is available [here](#). After editing you will need to start the registration process from step # 3.' The 'Owner/Operator Information' form contains the following data: Contact Name: Patricia Grady, Company: G&A SOLUTIONS, Address: po box 5304, Springfield, VIRGINIA, 22150, UNITED STATES, Telephone: 1- 571 - 5775077, and Fax: (blank). The 'Official Correspondent Information' form contains: Contact Name: Patricia Grady, Company: G&A SOLUTIONS, Address: po box 5304, Springfield, VIRGINIA, 22150, UNITED STATES, Telephone: 1 571 - 5775077, Fax: (blank), E-mail: patricia.grady@fda.hhs.gov, and DUNS Number: 123456789.

Facility Information

Owner/Operator & Official Correspondent

US Agent Information

Device Listings

Imported Products & Mfrs

Instructions for how to edit the owner/operator and official correspondent information is available [here](#). After editing you will need to start the registration process from step # 3.

Review Registration Information page.

Owner/Operator Information

Contact Name:	Patricia Grady
Company:	G&A SOLUTIONS
Address:	po box 5304 Springfield, VIRGINIA, 22150, UNITED STATES
Telephone:	1- 571 - 5775077
Fax:	

Official Correspondent Information

Contact Name:	Patricia Grady
Company:	G&A SOLUTIONS
Address:	po box 5304 Springfield, VIRGINIA, 22150, UNITED STATES
Telephone:	1 571 - 5775077
Fax:	
E-mail:	patricia.grady@fda.hhs.gov
DUNS Number:	123456789

Notes:

Owner/Operator Information & Official Correspondent Information: Instructions for how to edit this information is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053185.htm#11>. After editing, you will need to start the registration process from step #3.

US Agent

The screenshot displays a web interface for updating US Agent information. On the left is a vertical sidebar with five buttons: "Facility Information", "Owner/Operator & Official Correspondent", "US Agent Information", "Device Listings", and "Imported Products & Mrs". The main content area shows the "United States Agent Information" page with an "EDIT" button highlighted in a yellow box. A callout bubble points to this button with the text "Click EDIT to open the Update US Agent Information page." Below this, a form titled "Update U.S. Agent Information" is shown. It includes a "FACILITY" field with the value "GRADY EAST MANUFACTURING, SHANGHAI, SHANGHAI, CHINA". A red note states "Fields marked with an asterisk (*) are required." The form contains fields for "Contact Name:" (Steven Nagy), "Contact Title:" (Mr), "Business Name:" (SANCO), "Address:" (12345 Rockville Pike), "City:" (Rockville), and "State:" (Maryland). A "Phone:" field contains "301 - 7701234". At the bottom of the form, a "Review Changes" button is highlighted in a yellow box, with a callout bubble pointing to it that says "Click Review Changes when you are done." A "BACK" button is also visible.

United States Agent Information **> EDIT**

Click EDIT to open the Update US Agent Information page.

Contact Name: Steven Nagy
Contact Title: Mr
Business Name: SANCO
Address: 12345 Rockville Pike
Rockville, Maryland, 20852, UNITED STATES
Phone: 301 - 7701234
Fax:
Annual Re-Registration:
Get Help

Update U.S. Agent Information

FACILITY: GRADY EAST MANUFACTURING, SHANGHAI, SHANGHAI, CHINA

Fields marked with an asterisk (*) are required.

Contact Name:* Steven Nagy
Contact Title: Mr
Business Name: SANCO
Address: 12345 Rockville Pike
City:* Rockville
State: Maryland

Click Review Changes when you are done.

< BACK **> Review Changes**

Notes:

US Agent Information: Click "EDIT" to change information on the Update US Agent Information page. When you are done, click "Review Changes" to make sure your changes are correct.

Device Listings

The screenshot shows a software interface for managing device listings. On the left is a vertical sidebar with five menu items: Facility Information, Owner/Operator & Official Correspondent, US Agent Information, Device Listings (highlighted), and Imported Products & Mfrs. The main content area is titled 'Device Listings' and contains a table with columns: Listing Number, Premarket Submission Number/Type, Product Codes, and Device Name. A callout box points to a button '> ADD, EDIT OR DELETE' at the top right of the table. Another callout points to the table header with the text 'Click ADD, EDIT OR DELETE to change Device Listings information...'. Below the table, a facility name is displayed: 'FACILITY: GRADY EAST MANUFACTURING, SHANGHAI, SHANGHAI, CHINA'. Below this is another table with columns: Listing Number, Premarket Submission Number/Type, Product Code(s), and Device Name(s). A callout points to a radio button next to a listing, with the text '..then, click radio button to select device.'. To the right of this table, a callout points to buttons '> REMOVE this PRODUCT from FACILITY'S LISTINGS', '> EDIT SELECTED LISTING', and '> ADD NEW PRODUCT', with the text 'To REMOVE, ADD, or EDIT device, click on appropriate button.'. At the bottom of the main area are three buttons: '< Go to OWNER OPERATOR LIST', '< CANCEL - RETURN to MAIN MENU', and '> CONTINUE'.

Device Listings > ADD, EDIT OR DELETE

Click ADD, EDIT OR DELETE to change Device Listings information...

Listing Number	Premarket Submission Number/Type	Product Codes	Device Name
D201492	Exempt	HQZ	FRAME, SPECTACLE

FACILITY: GRADY EAST MANUFACTURING, SHANGHAI, SHANGHAI, CHINA

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)
D201492	Exempt	HQZ	FRAME, SPECTACLE

..then, click radio button to select device.

To REMOVE, ADD, or EDIT device, click on appropriate button.

> REMOVE this PRODUCT from FACILITY'S LISTINGS

> EDIT SELECTED LISTING

> ADD NEW PRODUCT

< Go to OWNER OPERATOR LIST

< CANCEL - RETURN to MAIN MENU

> CONTINUE

Notes:

Device Listings: Click the radio button to select the device that needs updating. Then click "add, edit or delete" to add, remove or edit device information.

Imported Products

The screenshot shows a software interface for managing imported products. On the left is a vertical sidebar with five buttons: 'Facility Information', 'Owner/Operator & Official Correspondent', 'US Agent Information', 'Device Listings', and 'Imported Products & Mfrs'. The main area is titled 'Imported Products and Manufacturers' and contains a table with columns: 'Manufacturer(s) Name', 'Address', 'Product Code', 'Device Name', and 'Premarket Submission Number'. Two rows of data are visible, both for 'OTTO BOCK MANUFACTURING KONIGSEE GMBH'. A yellow box highlights an '> ADD OR DELETE' button at the top right. A callout bubble points to this button with the text 'Click ADD OR DELETE to open the Products Imported page.' Below the table, the section 'PRODUCTS IMPORTED:' contains a list of radio buttons next to the same manufacturer name. A callout bubble points to these buttons with the text 'Click radio button to select product.' Another callout bubble points to the same area with the text '...then click to remove products no longer imported.' A third callout bubble points to a '> REMOVE THIS PRODUCT' button with the text '...or to add a product from previously identified mfrs.' A fourth callout bubble points to a '> SEARCH & ADD MFR'S PRODUCTS' button with the text '...or to add product from new mfr.' At the bottom, there are three buttons: '< Go to LIST OF MFRS ALREADY IDENTIFIED BY OO', '< CANCEL - RETURN to MAIN MENU', and '> CONTINUE'.

Manufacturer(s) Name	Address	Product Code	Device Name	Premarket Submission Number
OTTO BOCK MANUFACTURING KONIGSEE GMBH	LINDENSTRASSE 13, KONIGSEE, THURINGEN, D-07426, GERMANY	RAIR, MECHANICAL		K052081
OTTO BOCK MANUFACTURING KONIGSEE GMBH	LINDENSTRASSE 13, KONIGSEE, Thuringen, D-07426, GERMANY	IOR	WHEELCHAIR, MECHANICAL	K951847

PRODUCTS IMPORTED:

Product Code	Device Name	Premarket Submission Number
RAIR, MECHANICAL		K052081
WHEELCHAIR, MECHANICAL		K951847

Notes:

Imported Products and Manufacturers: Click "ADD OR DELETE" to remove products that are no longer imported, to add a product from a list of previously identified manufacturers, or add a product from a new manufacturer."

Certificate

The screenshot shows a web form titled "Certification Statement". At the top left, there is a checkbox that is checked, with a callout box pointing to it that says "8. Read statement and click the checkbox...". Below this, there is a large text area containing an "Important Notice" about visiting the FDA User Fee website and paying for a facility prior to registering. A callout box points to this notice, stating "If an error message pops up, check the box above." At the bottom of the text area, there is another callout box that says "...then click Submit." Below the text area, there are three buttons: "< BACK to DISPLAY REGISTRATIONS", "< CANCEL - RETURN to MAIN MENU", and "> SUBMIT". The "SUBMIT" button is highlighted with a yellow border. A small "Windows Internet Explorer" error dialog box is also visible, with the message "Click the Certification Statement box." and an "OK" button.

Notes:

8. On the Review Registration Information page, scroll down to the Certification Statement. Review the statement and click the checkbox and then "Submit." If you get an error message, click the checkbox next to the statement before trying to resubmit.

Payment

Annual Re-Registration

Enter Payment Confirmation Number

Enter your Payment Identification Number (PIN) and Payment Confirmation Number (PCN) for each registration shown below.

The PIN is a 8-digit number beginning with the number 5. The PCN is an 8-digit number beginning with the two character fiscal year - for 2013, the PCN begins with "13".

You must have a separate PCN for each registration. To pay your annual registration user fee, you must visit the [FDA User Fee website](#) and enter your PIN and PCN. After completing registration, if you have paid for your registration(s) and displayed your numbers by visiting the [FDA User Fee website](#).

9. Enter the PIN & PCN...

Registration Number	Address	PIN	PCN
Active, Waiting for Registration Number Assignment	Grady East Manufacturing, 7001 Zongchun Road, B Building, Suite 512, Shanghai, CHINA	<input type="text"/>	<input type="text"/>

...then click Submit

< BACK

> SUBMIT

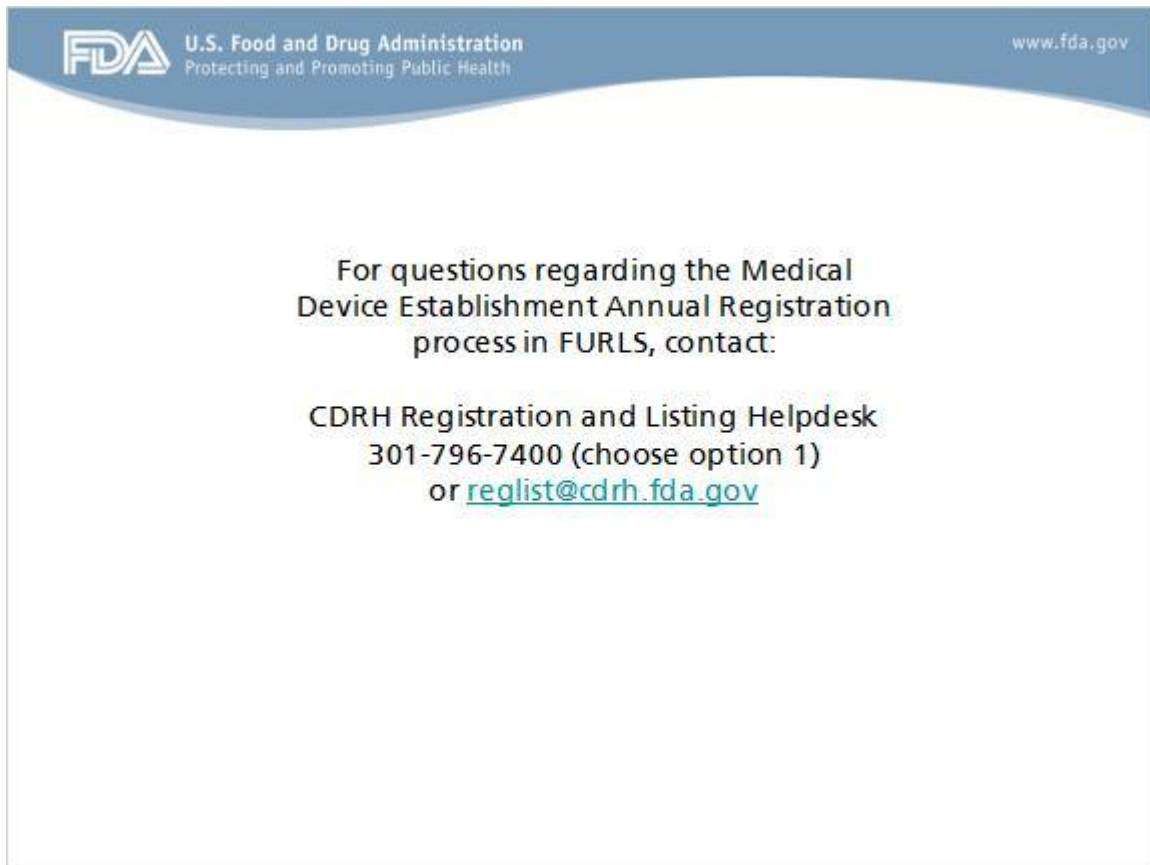
< RETURN to MAIN MENU

< RETURN to ACCOUNT MANAGEMENT

Notes:

9. On the Enter Payment Confirmation Number page, enter the PIN & PCN. Note that you must have a unique PIN & PCN to register each facility. When you click Submit, print out a copy of the annual registration for your records.

Contact Information



Notes:

Please contact us if you have any questions about the re-registration process.